

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evidence for Better Lives Study: A comparative birth-cohort study on child exposure to violence and other adversities in eight low- and middle-income countries – Foundational Research (Study Protocol).
AUTHORS	Valdebenito, Sara; Murray, Aja; Hughes, Claire; Băban, Adriana; Fernando, Asvini; Madrid, Bernadette J.; Ward, Catherine; Osafo, Joseph; Michael, Dunne; Sikander, Siham; Walker, Susan; Thang, Vo Van; Tomlinson, Mark; Fearon, Pasco; Shenderovich, Yulia; Marlow, Marguerite; Chathurika, Deshanie; Taut, Diana; Eisner, Manuel

VERSION 1 – REVIEW

REVIEWER	Iina Badr Azusa Pacific University
REVIEW RETURNED	12-Nov-2019

GENERAL COMMENTS	A well written proposed astudy that is of great interest to researchers.
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REVIEWER	Damion Grasso University of Connecticut, United States
REVIEW RETURNED	23-Dec-2019

GENERAL COMMENTS	<p>The purpose of submitted manuscript is to publish a multi-site, multi-country prospective birth cohort study to study prenatal exposure to violence and its impact on young children: The Evidence for Better Lives Study (EBLS). The actual study is slated to begin in 2020. The reviewed study protocol reflects the third stage of a 4-stage process, the final being the full study. The third stage (foundational study) occurred between July 2018-December 2019 with the goals of piloting data collection on 1200 families to address 7 aims, including strategies for recruitment, feasibility of recruiting fathers, obtain initial sample prevalence estimates, etc. The manuscript provides a sufficient overview of the literature motivating the larger study. It is well-written and clear. The figures and tables are clearly presented, informative, and augment comprehension of the text. Less explicit is how the first two stages of the process have informed the development of the stage-4 protocol. Perhaps a section summarizing why the first two stages were necessary and how they influenced design and implementation of stage 3. Another area that may need further description is the analytic section; however, not having reviewed a study protocol for publication before, I will defer to the editorial team's discretion. Is it important to know estimated effect sizes and power analyses? Since it is primarily descriptive statistics and measurement models proposed for this stage, this may be not be much of an issue. Finally, while the authors provide</p>
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	background information to motivate why a study on prenatal violence exposure is necessary, less motivated are the biological mechanisms being tested (e.g., inflammation). Perhaps consider a paragraph that links biological indicators to prenatal factors that may be associated with explaining the link between violence and birth/child outcomes.
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REVIEWER	Nick Metheny St. Michael's Hospital, Toronto, Canada
REVIEW RETURNED	28-Feb-2020

GENERAL COMMENTS	<p>This protocol of the foundation research to the Evidence for a Better Life (EBLS) study is an important entrée to the main study that is to follow. This is an important topic that deserves more substantial and rigorous inquiry, and I applaud the authors on this massive undertaking. I feel the article is largely well written, but there are some changes and clarifications that are needed before it is ready for publication.</p> <p>Intro:</p> <ul style="list-style-type: none"> • Major <ul style="list-style-type: none"> o It is sometimes unclear whether the authors are referring to violence occurring against women who are pregnant or violence against children in early childhood. A thorough review of the language throughout the introduction to specify the target of violence would be helpful. • Minor <ul style="list-style-type: none"> o “prenatal exposure to prenatal IPV” is confusing wording. Consider changing to something like “the effect of prenatal IPV on early child development” o P 5 Line 42-43: the authors might think of providing an example of such a preventative policy for readers less familiar with this literature o P 6 line 33: the authors should be more specific that they are talking only about violence occurring in the current pregnancy <p>Methods:</p> <ul style="list-style-type: none"> • Major <ul style="list-style-type: none"> o The authors fail to make a substantive case for why follow-up in this study is limited to the first 6 months of the child’s life. I don’t doubt there are valid reasons, but there should be made more clear o Why did the authors choose two countries from the same region (Philippines and Sri Lanka) to sample male partners? A rationale for this would be appreciated. o The authors mention “trained female fieldworkers”. What type of training did they undergo? By whom? Were international guidelines on research with women experiencing violence followed? o IPV is directly linked to reduced uptake of antenatal care, meaning the samples used here are unlikely to be representative of those experiencing violence. Noting this as a significant limitation is necessary. o Authors should be sure to include the fact that multi-site studies require multilevel models to account for the nested structure of the data. Additionally a mention of actor-partner interdependence modeling (APIM) would add to the analysis section regarding father’s questionnaires • Minor <ul style="list-style-type: none"> o P9 Line 29: a citation of the World Bank classification for LMIC (or whichever classification body the authors used) is needed here. o P9: Point “ii” is used twice o P12 Line 36: A separate table or appendix outlining the incentives for each study site would be helpful for transparency as well as for
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	<p>future multi-country protocols. Additionally, information on whether incentives were different for mothers vs. fathers would be helpful</p> <ul style="list-style-type: none"> o P 12 line 11: Considering the countries studied are diverse, multi-ethnic societies, it is important to know into which languages the instruments were translated to ensure a broad sampling frame. Also, In order to include ethnic and linguistic minority women (who may be at higher risk of IPV due to their subaltern status in the community), the authors should consider making the instrument available in more than just the most common language spoken in a given community. <p>Discussion</p> <ul style="list-style-type: none"> • Minor: <ul style="list-style-type: none"> o P 18 Line 51: a citation and reference to the specific SDGs being mentioned would be helpful here
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

No revisions suggested.

Reviewer 2

Less explicit is how the first two stages of the process have informed the development of the stage-4 protocol. Perhaps a section summarizing why the first two stages were necessary and how they influenced design and implementation of stage 3.

Response: Figure 1, describe the stages and its aims. In page 5, we have added a paragraph saying: While the first two stages helped to articulate the aims of the project and to select the study sites, EBLS-FR tests the main components for the full study (e.g., recruitment, data collection instruments, translations).

Finally, while the authors provide background information to motivate why a study on prenatal violence exposure is necessary, less motivated are the biological mechanisms being tested (e.g., inflammation). Perhaps consider a paragraph that links biological indicators to prenatal factors that may be associated with explaining the link between violence and birth/child outcomes.

Response: The motivation is stated in pages 4 and 19. The paragraph says: “To complement participants’ reports of their experiences and behaviours, the study will also include biological data collection to examine biological pathways related to violence and health. This will allow us to test for the first time the combined role of systemic inflammation and the HPA axis on mediating links between p-IPV and maternal and birth outcomes. It has been argued that highlighting the biological effects of social issues (such as violence) can be particularly effective in motivating policy change (e.g., Mcdade, Williams, & Snodgrass, 2007). EBLS-FR data collection tools and datasets from eight countries can also benefit the broader research community working on violence prevention”.

Reviewer 3

This protocol of the foundation research to the Evidence for a Better Life (EBLS) study is an important entrée to the main study that is to follow. This is an important topic that deserves more substantial

and rigorous inquiry, and I applaud the authors on this massive undertaking. I feel the article is largely well written, but there are some changes and clarifications that are needed before it is ready for publication.

Intro:

- Major

It is sometimes unclear whether the authors are referring to violence occurring against women who are pregnant or violence against children in early childhood. A thorough review of the language throughout the introduction to specify the target of violence would be helpful.

Response: The language has been revised to clarify that EBLs-FR is a pilot project involving measures of prenatal exposure to violence. Other measures relating to exposure to violence during childhood will be tested in subsequent stages of the project. See pages 2 (abstract) and page 7 (aims of the study).

- Minor

Prenatal exposure to prenatal IPV” is confusing wording. Consider changing to something like “the effect of prenatal IPV on early child development”

Response: We have revised the wording as suggested. See page 4.

P5 Line 42-43: the authors might think of providing an example of such a preventative policy for readers less familiar with this literature.

Response. Thank you for your suggestion. We have added an example of Jamaica’s National Parenting Policy that was guided by the findings from several longitudinal studies in Jamaica. In page 5 the following paragraph has been added: “For example, longitudinal studies in Jamaica have found that limited stimulation of children in the home and high levels of parental stress to be negatively related to child outcomes, including cognitive function and behaviour (23). These findings guided the development of Jamaica’s National Parenting Policy, public messaging, and programmes for parents”.

P 6 line 33: the authors should be more specific that they are talking only about violence occurring in the current pregnancy

Response: The adapted version of the the scale measuring p-IPV (García-Moreno et al. 2015), collects data on pre-natal exposure to IPV. The specific question is framed in the “last six months”. A paragraph has been added in page 14 to clarify that the pre-natal IPV refers to the current pregnancy.

Methods:

- Major

-The authors fail to make a substantive case for why follow-up in this study is limited to the first 6 months of the child’s life. I don’t doubt there are valid reasons, but there should be made clearer.

Response: The follow-up re-tests key variables for the EBLs-FR such as mental health and mothers’ birth memories. A main aim of the follow-up was to test the process of re-contacting participants and retaining them post-birth. The nature of a pilot study has restricted the follow up to a maximum of six months after birth. However, the main study is expected to follow participants during the first five years of life. A paragraph explaining this has been added in page 13.

-Why did the authors choose two countries from the same region (Philippines and Sri Lanka) to sample male partners? A rationale for this would be appreciated.

Response: Sites were asked to volunteer for testing the father’s questionnaire based on the feasibility of contacting and interviewing fathers. Only the Philippines and Sri Lanka could complete these interviews. A paragraph explaining this has been added in page 10.

The authors mention “trained female fieldworkers”. What type of training did they undergo? By whom? Were international guidelines on research with women experiencing violence followed?

Response: In page 12, we describe the training offered to fieldworkers. The contents of the training include the international guidelines on research with women experiencing violence by the World Health Organisation. The following paragraph has been added: “Data are collected by fieldworkers who have received standardised 40-hours of in-person training covering topics such as recruitment, consent, data collection and storage procedures, principles of research ethics, referral procedures, and management of risk and difficult situations in the field (e.g., participant distress or unsafe situations). Special emphasis was given to skills and strategies for addressing women experiencing violence (46–48). The contents of the training were developed and approved by the EBLIS consortium and they are described in the fieldworker handbook specifically developed for EBLIS-FR. Training at each site was carried out by the local research coordinator who had been previously trained by the Cambridge team”.

IPV is directly linked to reduced uptake of antenatal care, meaning the samples used here are unlikely to be representative of those experiencing violence. Noting this as a significant limitation is necessary.

Response: We have added a note of the fact that IPV is related to antenatal care uptake and that our sample may, therefore, under-represent women experiencing abuse to the ‘Recruitment, screening, consent and incentives’ section (page 11).

Authors should be sure to include the fact that multi-site studies require multilevel models to account for the nested structure of the data. Additionally, a mention of actor-partner interdependence modelling (APIM) would add to the analysis section regarding father’s questionnaires.

Response: We have expanded the ‘data analysis’ section to note the need for multi-level or multi-group models when analysing the multi-country data (p.16). We have also added the suggestion that actor-partner interdependence model could be used to analyse the mothers’ and fathers’ data in conjunction to understand the effects of mothers and fathers on each other (pages 16-17)

• Minor

P9 Line 29: a citation of the World Bank classification for LMIC (or whichever classification body the authors used) is needed here.

Response: The following citation has been added.

OECD. (2020). DAC List of ODA Recipients Effective for reporting on 2018, 2019 and 2020 flows. Retrieved March 5, 2020, from https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/DAC_List_ODA_Recipients2018to2020_flows_En.pdf

P9: Point “ii” is used twice

Response: This has been corrected.

P12 Line 36: A separate table or appendix outlining the incentives for each study site would be helpful for transparency as well as for future multi-country protocols. Additionally, information on whether incentives were different for mothers vs. fathers would be helpful.

Response: Information describing incentives in each site has been included in Table 2. Incentives for mothers and fathers were similar.

• Minor:

P 12 line 11: Considering the countries studied are diverse, multi-ethnic societies, it is important to know into which languages the instruments were translated to ensure a broad sampling frame. Also, in order to include ethnic and linguistic minority women (who may be at higher risk of IPV due to their subaltern status in the community), the authors should consider making the instrument available in more than just the most common language spoken in a given community.

Response: The instrument has been translated into Urdu, Afrikaans, IsiXhosa, Romanian, Filipino (Tagalog), Sinhala, Tamil, Vietnamese and Twi. The most widely spoken languages in each city were selected. See note 2 in page 12

P 18 Line 51: a citation and reference to the specific SDGs being mentioned would be helpful here

Response: Citation included. See references below.

UN. (2019). The Sustainable Development Goals Report. New York. Retrieved from <https://unstats.un.org/sdgs/report/2019/The-Sustainable-Development-Goals-Report-2019.pdf>

VERSION 2 – REVIEW

REVIEWER	Damion Grasso University of Connecticut School of Medicine
REVIEW RETURNED	08-May-2020
GENERAL COMMENTS	The authors were responsive to the reviewers' concerns. No further modifications are necessary.